IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

SPINE SOLUTIONS, INC., a Delaware Corporation; SYNTHES SPINE COMPANY, L.P., a Delaware Limited Partnership; and SYNTHES, INC., a Delaware Corporation,	)	
Plaintiffs-Counterdefendants,	)	
v.	)	**No. 07-2175 JPM-dkv**
MEDTRONIC SOFAMOR DANEK, INC., an Indiana corporation, and MEDTRONIC SOFAMOR DANEK USA, INC., a Tennessee corporation,	)	
Defendants-Counterclaimants.	)	

AMENDED ORDER DENYING MEDTRONIC'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW AND ALTERNATIVE MOTION FOR A NEW TRIAL

Before the Court is Defendants Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc.'s (collectively "Medtronic") Renewed Motion for Judgment as a Matter of Law and Alternative Motion for a New Trial ("Medtronic Mot."), filed December 22, 2008. (Docket Entry ("D.E.") 420.) Plaintiffs Spine Solutions, Inc.; Synthes Spine Company; and Synthes, Inc.'s (collectively "SSI") filed a Memorandum in Opposition to Medtronic's Renewed Motion for Judgment as a Matter of Law and Alternative Motion for a New Trial ("SSI Response") on January

23, 2009. (D.E. 439.) Medtronic filed a Reply Memorandum in Support of Medtronic's Renewed Motion for Judgment as a Matter of Law and Alternative Motion for a New Trial ("Medtronic Reply") on February 10, 2009 (D.E. 449) and a Citation of Supplemental Authority on February 18, 2009 (D.E. 453). SSI then filed a Memorandum in Response to Medtronic's Reply Memorandum and Citation of Supplemental Authority, Regarding Medtronic's Renewed Motion for Judgment as a Matter of Law and Alternative Motion for a New Trial ("SSI Sur-reply") on March 11, 2009 (D.E. 463) and a Supplemental Citation of Authority on August 17, 2009 (D.E. 492). For the reasons that follow, Medtronic's motion is DENIED.

I. BACKGROUND

SSI and Medtronic manufacture and sell spinal implants used in spinal surgery. (Pretrial Order (D.E. 390) 3.) In 1994, SSI obtained U.S. Patent No. 5,314,477 (the "'477 patent") for an artificial disc device, of which the commercial embodiment is the ProDisc I. (Id. at 8-9.) Dr. Thierry Marnay is listed as the sole inventor on the '477 patent. (Id. at 9.) In 2005, SSI obtained U.S. Patent No. 6,936,071 (the "'071 patent"), also for an artificial disc device, of which the commercial embodiment is an artificial disc device known as the ProDisc II. (Id.) Marnay and Boris Beyersdorff are listed as the inventors on the '071 patent. (Id.)

Whereas the '477 patent teaches the use of two anchors on both the upper and lower part of the implant to secure the device to adjacent vertebrae (see Trial Ex. 7, col. 7), the '071 patent teaches the use of a single anchor for the same purpose (Trial Ex. 1, col. 7). The single anchor is referenced in claim 1 of the '071 patent, and the parties' dispute in the case centers on this claim. The full claim reads as follows:

> 1. An intervetebral implant insertable between adjacent vertebrae, comprising,
>
> an upper part having an upper surface for engaging a vertebrae and a lower surface which includes a rounded portion,
> a lower part having a lower surface for engaging a vertebrae and an upper surface portion in operative engagement with the rounded portion of the upper part,
> said implant being constructed to be the sole implant in its intervertebral space,
> the implant having a lead end which leads as the implant is inserted along a path into the intervertebral space and a trailing end opposite the lead end, and lateral planes which pass through the outermost boundaries of the implant and parallel to the said path, and
> a single anchor on each of the upper surface of the upper part and the lower surface of the lower part, each said anchor being elongated, having a height greater than its width, and located along a line parallel to said path, the two anchors lying essentially in the same vertical plane, which plane is essentially midway between said lateral planes, each said anchor being adapted to enter a groove in the adjacent vertebrae as the implant moves along said path into the intervertebral space, to anchor its respective part to the vertebrae which its surface engages.

(Trial Ex. 1, col. 6-7.)

Medtronic manufactures and sells three artificial disc devices that pertain to the instant case: the Maverick, the A-MAV, and the O-MAV (collectively referred to as the "Maverick"). (Pretrial Order at 9.) SSI initiated the instant lawsuit against Medtronic on March 7, 2007, asserting that the Maverick infringes the '071 patent. (See generally, Compl. (D.E. 1).) In response, Medtronic asserted that the claims of the '071 patent are obvious in light of the prior art, thereby rendering the '071 patent invalid. (Pretrial Order 7.) On December 5, 2008, a jury found that Medtronic did not prove by clear and convincing evidence that the claims in the '071 patent were obvious. (Jury Verdict Form 1.) The jury found Spine Solutions was entitled to $5,783,246 in lost profits and $1,643,681 in royalties. (Id. at 2-3.) Furthermore, the jury found Spine Solutions proved by clear and convincing evidence that Medtronic's infringement of the '071 patent was willful. (Id. at 3.)

II. ANALYSIS

In its motion, Medtronic moves for (A) judgment as a matter of law ("JMOL") or, in the alternative, (B) a new trial. Each request is addressed in turn.

A. Judgment as a Matter of Law

Federal Rule of Civil Procedure 50 provides that a court should grant a motion for JMOL when "a party has been fully

heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a)(1). To prevail on a renewed motion for JMOL following a jury trial, a party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984) (alteration in original)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F.2d at 893. In essence, the proper inquiry is "whether a reasonably jury, given the record before it viewed as a whole, could have arrived at the conclusion it did." Dawn Equip. Co. v. Ky. Farms Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998) (citing Tex. Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1563 (Fed. Cir. 1996)).

Medtronic disputes the jury's finding that (1) the claims of the '071 patent were non-obvious, (2) Medtronic willfully infringed the '071 patent, and (3) SSI was entitled to lost profits. The Court addresses each issue below.

1. Obviousness of the Claims of the '071 Patent

Medtronic first seeks JMOL on the issue of obviousness. Under 35 U.S.C. § 103,

> [a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a). An obviousness inquiry under 35 U.S.C. § 103(a) is a question of law based on underlying questions of fact. Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1348 (Fed. Cir. 2000). These factual inquiries are: (a) the scope and content of the prior art, (b) the level of ordinary skill in the art, (c) the differences between the prior art and the claimed invention, and (d) the extent of any "secondary considerations." Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966).

In KSR Int'l Co. v. Teleflex, the Supreme Court affirmed the use of the Graham factors but also emphasized that an obviousness inquiry should not be reduced to "rigid and mandatory formulas." 550 U.S. 398, 419 (2007) (rejecting the "teaching, suggestion, or motivation" test under which a patent claim is obvious only if there is some motivation or suggestion to combine the prior art teachings). The Court found that "[u]nder the correct analysis, any need or problem known in the

field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." Id. at 420. The Court reasoned that "[c]ommon sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id.

Despite the Court's relaxation of the obviousness inquiry, it made clear that a party must do more than simply identify each element of a patent in the prior art. Id. at 418 ("[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.") The Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in a way the claimed new invention does." Id. at 418. Thus, "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established function." Id. at 417.

Medtronic essentially makes three arguments: (a) the distinguishing features of the '071 patent were present in the Nobuo reference and non-spinal prior art, (b) the '071 claims were a predictable use of the prior art, and (c) SSI's evidence

of secondary considerations is insufficient to overcome Medtronic's prima facie case of obviousness.

a. Presence of the '071 Patent Elements in the Prior Art

Medtronic argues that (i) the '071 patent elements were disclosed by a combination of the '477 patent and the Nobuo reference and (ii) non-spinal prior art discloses use of a single anchor.

i. Nobuo Reference

Medtronic first asserts that the Nobuo reference and the '477 patent render the claims of the '071 patent obvious. The Nobuo reference describes a device that replaces a damaged vertebra and has a single anchor affixed to its upper and lower portions. (Trial Ex. 82 at SSMED0353620; Trial Tr., Dec. 1, 2008, 1035:10-1036:15.) Medtronic notes that only claim 1 of the '071 patent differentiates it from the '477 patent. Medtronic concludes that because the Nobuo device has two anchors in the same vertical plane, the combination of these elements as described by the '071 patent is obvious. SSI does not dispute the assertion that only claim 1 distinguishes the '071 patent from the '477 patent but does contest Medtronic's argument that the Nobuo reference combined with the '477 patent makes obvious the '071 patent.

At trial, the jury heard several differences between the Nobuo device and the spinal implant taught by the '071 patent. Paul Duchyene, SSI's expert witness in the field of orthopedic device fixation, testified that the Nobuo device was used to "replace an entire vertebra," "does not move within" the spine, and is used to "maintain [spinal] length" following removal of a damaged vertebra. (Trial Tr., Dec. 1, 2008, 957:22-958:8.) He further noted that the device is bonded to "healthy vertebrae." (Id. at 1042:23-25.) By contrast, evidence at trial showed that the ProDisc II is attached to adjacent vertebrae that are often weakened due to acid released by a degenerated disc. (Trial Tr., Nov. 25, 2008, 407:23-408:8, 409:11-24, 410:24-412:23.)

Ducheyne specifically addressed the discrepancies between the projections on the Nobuo device and the anchors described by the '071 patent in one exchange with Medtronic's counsel:

> Q. So those – The Nobuo reference at least supplies the missing elements that we talked about in connection with claim 1, correct, sir?
>
> A. No, because there are a number of other discrepancies here in the description of the keel that are not yet clear from the Nobuo, and actually as I indicated, there are forces that act on these devices, and that's clearly a very different situation here with the Nobuo as it is with the infringing of Dr. Marnay.
>
> Q. I'm asking you, sir, not about forces, I'm asking you about whether the Nobuo reference shows the missing elements that are actually claimed in the '071 patent, claim 1?

> A. Let me approach so that I see what is in there. There are a number of – You may remember from claim 1 in the '071 patent that the description of the single anchors was very extensive and a window for that. What I see of the Nobuo, these are not plate-like elements that are capable of achieving that function as is crafted in the investigation by Marnay, so, therefore, the answer is no.
>
> Q. Didn't you just tell me that, in fact, these two projections that are in the middle, which are in the same vertical plane with respect to one another, are used to anchor the device to bone in the spine, the vertebrae?
>
> A. With the use of bone cement because, without use of bone cement, there wouldn't be any anchor.

(Id. at 1036:16-1037:17.)

SSI introduced additional evidence that the Nobuo device requires cement to bond to non-adjacent vertebrae.[1] Ducheyne testified that using bone cement to stabilize the Nobuo device is "opposite" the use of the press fit method of the '071 patent. (Trial Tr., Dec. 1, 2008, 957:1-11.) Medtronic's expert witness Stephen Cook similarly testified that the use of bone cement is different than the press fit of the '071 patent. (Trial Tr., Dec. 4, 2008, 1648:24-1649 (agreeing that bone cement is "different than a situation where you would have a press fit").) Furthermore, both Ducheyne and Cook testified

[1] In addition to bone cement, the Nobuo device relies on mechanical tightening to achieve fixation. The reference states that "two flat plates . . . are tightly fitted onto the two endplates while continuing to rotate the length adjusting ring 19, to complete mounting the artificial vertebra." (Trial Ex. 82 at SSMED0353625-626; see also SSI Sur-Reply 3 n.1 (comparing the tightening device to a car jack).)

that the use of bone cement is not appropriate for total disc replacements. (See Trial Tr., Dec. 1, 2008, 956:17-597:11 (Ducheyne testifying that "you don't want cement" and "we absolutely do not want to use" cement with press fit); Trial Tr., Dec. 3, 2008, 1649:23-1650:1 (Cook agreeing that "if cement can be avoided with a disc replacement device, it would be preferred to be avoided").)[2]

From this evidence, a reasonable jury could have found that a person of ordinary skill in the art would conclude that the Nobuo reference does not disclose the single anchor described by the '071 patent.[3]

ii. Non-Spinal Art

Medtronic next argues that non-spinal prior art and the '477 patent disclose all the elements of the '071 patent. Specifically, Medtronic contends that a person of ordinary skill

[2] Medtronic asserts that because claim 1 of the '071 patent has no limitation regarding whether the device is press-fit or implanted with bone cement, the patent does not preclude any additional anchoring. Medtronic's argument strays from the proper obviousness inquiry, however. Whether claim 1 of the '071 patent encompasses addition of bone cement to a device or the lack of a press-fit method of insertion does not pertain to the issue of what was obvious based on teachings in the prior art.

[3] Medtronic notes that the PTO had only an abstract of the Nobuo reference and lacked a full translation. Medtronic argues that without a full translation, a patent examiner cannot be considered to have considered the full teachings of the patent and that the abstract omitted "critical" information about the single keel of the device achieving fixation to the center of a vertebra. (Medtronic Reply 7-8.) Medtronic, however, has not pointed to any evidence that the full translation contains information challenging the notion that Nobuo is distinct from the '071 patent because of its use of additional fixation and the fact that unlike the ProDisc II, it replaces an entire vertebra and is attached to healthy non-adjacent vertebrae.

would look to knee, shoulder, and hip devices when designing an artificial spinal disc. Medtronic states that these references use a single, central anchor to fix a joint replacement to bone – the exact problem being solved in the claims of the '071 patent. Thus, Medtronic asserts, "the pertinence of non-spinal art is undisputed."[4] (Medtronic Mot. 10.)

At trial, however, the jury heard testimony that there are important differences between fixation devices used in peripheral joints and those that would work in the spine. (See Trial Tr., Dec. 1, 2008, 947:10-949:1 (Ducheyne testifying that "even though we know about knee prosthesis and hip prothesis . . . and how these are set in bone" they do not "really tell you how you have to solve [the fixation problem] for the spine"); 950:25-951:19 (Ducheyne testifying that "knowing that [fixation]

[4] To support this assertion, Medtronic highlights Ducheyne's testimony on cross-examination, in which he stated that

> [i]t is clear that as an orthopedic surgeon, even if one becomes either a hip surgeon or a spine surgeon, that one goes through training, and it takes five years plus sometimes that one goes through training where one is exposed to all the various anatomical parts of the body, where orthopedic surgeons perform these procedures, including the hip, the knee, the bones, the fingers, the spine and what have you [. . . .] So, therefore, information within, for instance, the – the hand surgery field is available to even a spine surgeon. And so there is no restriction for, for instance, knee surgeons to look at what is done in terms of – of – of ligament repair, bone fracture repair.

(Trial Tr. Dec. 1, 2008, 1031:2-14.) Importantly, while Ducheyne noted that orthopedic surgeons would likely be familiar with knees, hips, shoulders, and spines, his testimony does not state that a person skilled in the art would have looked to peripheral joints to find a spinal anchor. Ducheyne's testimony therefore does not support Medtronic's conclusion that the parties agree as to the importance of non-spinal prior art.

components exist [for knee devices] is not really enough to know how to solve the problem in the spine"); 956:6-957:11 (Ducheyne noting "important differences" – including the use of a heavy stem and bone cement – that differentiate a shoulder implant device from the '071 patent).) Given the differences between knee, hip, and shoulder implants and the '071 patent, a reasonable jury could conclude that a person of ordinary skill would not have looked to non-spinal art.[5]

Medtronic argues that SSI's continuing prosecution of the '071 patent before the PTO provides additional evidence of motivation to combine the '477 patent with the prior art. Medtronic notes that the Patent and Trademark Office ("PTO") rejected proposed claims disclosing a single anchor in SSI's continuation application based upon the use of single, central anchors in prior art in the toe, thumb, and ankle. (See Medtronic Mot. Ex. T, PTO Detailed Action, 12/2/08 at 5-6.) The PTO Examiner, however, did not provide any opinion regarding the

[5] Medtronic notes that Ducheyne admitted that the Yuan patent teaches the use of "one or more" fixation elements "located at any preselected positions" (Trial Tr. Dec. 1, 2008, 1051:12-21), and it argues that the reference provides express motivation to combine single anchor prior art with the '477 patent. The patent merely states that one or more protuberances may be used, however, and nowhere implies that using only one protuberance would be adequate to achieve fixation.

Medtronic also points out that the Yuan patent describes anchoring "adjacent vertebrae with press fit or cemented methods known in the art of joint replacement." (Trial Ex. 86 at Col. 6.) Medtronic contends that this teaching rebuts SSI's argument that the '477 patent should not be combined with the Nobuo reference because the Nobuo discloses the use of bone cement. The Court disagrees. There is no evidence that a person of ordinary skill in the art would find bone cement to be equivalent to the press fit method of the '071 patent or that a device that uses press-fit would also work with bone cement.

likelihood of success in using a peripheral joint structure in a total disc replacement device. (See generally, Medtronic Mot. Ex. N, Trial Ex. 43.) The PTO action therefore does not shed light on this key issue at trial.

b. Predictable Use of Prior Art

Medtronic also contends the evidence at trial established that SSI had a reason to use a single, central anchor design. The parties dispute two issues: (i) whether the prior art taught away from using a single, central anchor, thereby making the addition of the element to a device unforeseeable and (ii) whether the spinal disc replacement field was complex and filled with numerous design failures.

i. Teaching Away/Foreseeability

Medtronic argues that the use of a single, central anchor would have been foreseeable to one familiar with the prior art. Medtronic specifically notes that the Nobuo reference, the Pettine-Salib patent, and "a host" of non-spinal prior art references disclose discs anchored to the central part of the bone.[6]

[6] Medtronic addressed the issue of foreseeability in its Reply brief in response to arguments raised by SSI in its Response. In addition to the arguments addressed above, Medtronic contends that foreseeability is a secondary consideration of obviousness and has no bearing on the issue of the content of the prior art. In describing its "predictable result" inquiry, the Court in KSR referenced the "corollary principle" that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." KSR, 550 U.S. at 416. This Court therefore finds it appropriate to address the issue of foreseeability in this context.

Trial experts from both sides provided testimony supporting the proposition that the central portions of vertebral bodies are known to be weaker and would accordingly be expected to provide inferior fixation support compared to other parts of the bone. (Trial Tr., Nov. 15, 2008, 411:2-412:23 (Marnay describing how acid from damaged vertebra "makes the center part of the whole plate weaker"); 475:2-476:5 (Marnay describing how he expected the cortical bone, which is "far away from the midline," to provide the best fixation); 480:21-422:18 (Marnay describing that he first used a dual-anchor design because the center of the bone was weaker); 510:17-511:3; Trial Tr., Dec. 1, 2008, 947:9-948:19 (Ducheyne comparing the middle of a vertebral body to "dry wall").) Medtronic's expert Cook reiterated this notion, stating that "the weakest portion of the bone in the spine . . . is in the middle of the spine" and that the bone "gets stronger as you go out toward the periphery." (Trial Tr., Dec. 3, 2008, 1540:15-1542:4.) Thus, the jury heard evidence that the prior art taught away from using a single anchor in the middle of the bone to provide fixation.

Medtronic's reference to other devices is to no avail. As discussed above, supra Section II(A)(1)(a)(i), although it features a single, central anchor, the Nobuo device uses bone cement and mechanical tightening to provide additional fixation. The Pettine-Salib device similarly uses screws that penetrate

the peripheral cortical bone of the vertebral body. (See Trial Ex. 40 at Figure 2.) Therefore, the device is distinct from the '071 patent's anchor, which is positioned between vertebral endplates with weakened cortical bone. Accordingly, a reasonable jury could have concluded that the prior art taught away from using anchors without additional fixation devices to attach to the middle portion of the vertebrae.[7]

ii. Failure of Others

In addition, Medtronic argues that SSI has not adequately shown that the spinal disc replacement field presented a high degree of complexity that resulted in numerous design failures. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." KSR, 550 U.S. at 421; see also Ortho-McNeil Pharm., Inc. v. Mylan Lab., Inc., 520 F.3d 1358, 1364 (Fed. Cir. 2008) (interpreting KSR to hold that an invention is obvious when there is "a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness").

[7] In light of the Court's discussion of non-spinal prior art, see supra, Section II(A)(1)(a)(ii), Medtronic's assertion that "a host of prior art references outside of the spine" disclose a device anchored to the center of the bone is also to no avail.

Here, both parties introduced evidence that the spinal disc replacement field was highly complex. (See Trial Tr., Nov. 25, 2008, 346:18-347:24 (Marnay explaining why the spine is "one of the most difficult areas" of the body), 376:15-379:15 (Marnay describing that the spinal cord "is ultimate because it is life"); Trial Tr. Dec. 1, 2008, 927:2-929:7 (Ducheyne describing difficulties in achieving fixation), 950:6-951:19; Trial Tr., Dec. 3, 2008 (Cook agreeing that "many people had been working on this problem and the problem hadn't been solved").)

Furthermore, the jury heard evidence regarding the failures and shortcomings of other replacement discs, especially the Charité device. (See Trial Tr., Nov. 25, 2008, 469:5-470:4 (Marnay describing a report detailing expulsion difficulties with the Charité device), 491:7-21 (Marnay describing the difficulties with Charité's stabilization as well as expulsion issues); Trial Tr. Dec. 1, 2008, 892:2-8 (SSI expert Christopher Summa stating that "with my experience with the Charité, I thought it was too mobile . . . didn't provide enough stability to the spine," and caused "some issues with the facets"), 927:22-932:1 (Ducheyne discussing problems with fixation in the spinal disc replacement field in the past two decades); Trial Tr., Dec. 2, 2008, 1201:9-15 (SSI expert Robert Tollison describing expulsion and anchoring issues with the Charité).) In addition, the jury heard testimony that during the time the

'477 patent and '071 patent were being developed, few of the several proposed disc replacement designs were tested and most that were implanted in humans failed or were abandoned. (Trial Tr. Nov. 25, 2008, 454:8-14 (Marnay testifying that when the '477 patent was developed, "[t]here were few proposed [devices] and no[ne] successful," with most being just "a few cases with fails"); Trial Tr., Dec. 1, 2008, 935:5-16 (Ducheyne testifying that after 1997, there were "not too many" devices used in humans and that one Medtronic device "never really made it to use in humans" because "it did not work well enough"), 949:2-950:24 (Ducheyne testifying that in the mid-1990's "there [were] plenty of designs out there" and "plenty of ideas," which show that the field was "very complex"); Trial Tr., Dec. 3, 2008, 1612:13-1614:18 (Cook agreeing that "the task of designing an intervertebral disc replacement" is "challenging".)[8] Therefore, the jury had a reasonable basis to conclude that the spinal disc replacement field had multiple design options and was not easily traversed.

[8] Medtronic argues that SSI "has not demonstrated whether the reason some or any of these [failed] devices were or were not commercialized had anything to do with anchorage or were simply business decisions." (Medtronic Reply 11 (citing Dystar v. Testilfarben GMBH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1371-72 (Fed. Cir. 2006)). As discussed earlier in this section, experts testifying at trial commented on the fixation problems these various discs experienced, particularly the Charité.

c. Secondary Considerations

Medtronic argues that SSI's "reliance on alleged secondary considerations at trial is ultimately unavailing" in light of Medtronic's "strong prima facie case of obviousness." (Medtronic Mot. 11.) Based on the foregoing analysis, the Court disagrees that Medtronic has established a strong prima facie case of obviousness and therefore declines to grant Medtronic's motion on this basis.[9]

2. Willful Infringement

In addition to its obviousness defense, Medtronic seeks judgment as a matter of law as to the jury's finding that it willfully infringed the '071 patent. Willful infringement consists of both an objective and a subjective component. First, "a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent."

[9] In light of this finding, the Court need not address Medtronic's argument that the holdings in Boston Scientific Scimed, Inc. v. Cordis Corporation, Agrizap, Inc. v. Woodstream Corporation, and Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. apply to the instant case. In each of those cases, the court found there was a strong case of obviousness. See Boston Scientific, 554 F.3d 982, 991 (Fed. Cir. 2009) (finding that "the weak secondary considerations of nonobviousness do not overcome the strong *prima facie* showing that [a prior art reference] renders claim 8 of the '536 patent obvious"); Agrizap, 520 F.3d 1337, 1344 (Fed. Cir. 2008) (finding secondary considerations "insufficient to overcome the overwhelming strength of Woodstream's prima facie case of obviousness"); Leapfrog, 485 F.3d 1157, 1162 (Fed. Cir. 2007) ("[G]iven the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that claim 25 would have been obvious.").

For the same reason, the Court also declines to assess the merits of SSI's discussion of secondary considerations. (See SSI Response 8-11; SSI Sur-reply 10-11.)

In re Seagate Tech., LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007). Second, if the threshold objective standard is met, "the patentee must also demonstrate that this objectively-defined risk . . . was either known or so obvious that it should have been known to the accused infringer." Id.

Medtronic contends that neither prong was met by clear and convincing evidence.

a. Objective Prong

Medtronic argues that given its "strong" obviousness defense, SSI could not have proven by clear and convincing evidence that Medtronic acted despite an objectively high likelihood its actions constituted infringement. As stated above, the Court disagrees that Medtronic's obviousness case was "strong" and therefore does not view that as a basis to overturn a jury verdict that Medtronic acted despite an objectively high likelihood of infringement.[10]

b. Subjective Prong

Next, Medtronic asserts that the jury lacked sufficient evidence to find that Medtronic knew, or should have known, of a high likelihood that it was infringing the '071 patent. At

[10] Medtronic's additional arguments under the first Seagate prong are to no avail. Medtronic asserts that when developing the Maverick device, it relied on prior art that had not been considered by the patent examiner, but Medtronic admits that much of that art – including "various non-spine prior art references" – were admitted at trial. (Medtronic Mot. 14.) The jury therefore considered these additional references. Medtronic also renews its argument that the examiner did not have the full translation of the Nobuo reference during prosecution of the '071 patent, but the Court has rejected this argument. See supra, Section II(A)(1)(a)(i) n.3.

trial, the jury heard evidence that Medtronic thought it was important to "participate" in the disc replacement market (Trial Tr., Dec. 2, 2008, 1179:16-1180:19), that Medtronic unsuccessfully attempted to design a disc replacement design for several years (Trial Tr., Dec. 1, 2008, 927:2-929:7, 967:16-992:23, 991:14-992:23), that Medtronic did not have an anchor design prior to the time it saw Marnay's ProDisc II in 2001 (Trial Tr., Dec. 1, 2008, 1004:23-1005:12), that Medtronic officials said "the meeting and surgery opened my eyes" after seeing the ProDisc II at an international conference (Trial Tr. Dec. 1, 2008, 1003:3-21), and that Medtronic developed the Maverick in a "very fast way" and used a "me too" design (Trial Tr., Dec. 1, 2008, 1009:22-1010:8). Additionally, the jury heard evidence that Medtronic's design engineer "expressed doubts" about using a single anchor for fixation (Trial Tr. Dec. 1, 2008, 1006:19-1008:12), that Medtronic considered patent issues to be "secondary" and would "deal with that . . . if it arises" (Trial Tr., Dec. 2, 2008, 1138:13-20), and that Medtronic did not alter the design of the Maverick after learning of the '071 patent (Trial Tr., Dec. 2, 2008, 1287:2-1289:11).[11]

[11] This latter evidence of Medtronic's post-issuance conduct refutes Medtronic's argument that the finding of willfulness was based solely on pre-issuance conduct. (See Medtronic Reply 18.)

Medtronic contends that SSI "secretly" drafted claims in an effort to cover the Maverick and therefore any infringement was not willful. The Federal Circuit has held that it is not "in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of the patent application," Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988), and the jury was properly instructed on this point (see Jury Instructions 41). Medtronic also argues that the only post-issuance conduct upon which SSI relied was Medtronic's copying of one of the claims of the '071 patent to provide an interference with the PTO, but Medtronic's PTO submission affirmatively states that claims identical to claim 1 and other claims of the '071 patent are patentable over the prior art. (Trial Ex. 42 at SSI 0159607, 159730, 159768-771.) The jury therefore could have reasonably found that Medtronic's post-issuance conduct constituted willful infringement.

For these reasons, Medtronic's motion as to the jury's willful infringement finding is DENIED.

3. Lost Profits

Lastly, Medtronic moves for JMOL on the jury award of lost profits. Prior to trial, Medtronic moved to exclude evidence of lost profits by Synthes, Inc. and Synthes Spine, arguing that because there was no properly executed license between the

companies and Spine Solutions and that (at the time) neither company was a party to the lawsuit, their lost profits were irrelevant. At the same time, SSI moved to prevent Medtronic from introducing at trial any evidence of the corporate distinction between the companies. Following a telephone conference on the motions, the Court permitted SSI to amend its complaint to add Synthes, Inc. and Synthes Spine as Plaintiffs and denied both motions as moot. (Order Den. as Moot Pl. Spine Solutions, Inc.'s Mot. *in Limine* to Exclude Evidence and Arguments By Defs.' Relating to Corporate Distinctions Between Spine Solutions, Inc. and Synthes, Inc. and Synthes Spine for Purposes of Lost Profits Determination and Order Den. as Moot Medtronic's Mot. *in Limine* to Exclude Test. and Argument by Spine Solutions Relating to Damages Based on Lost Profits (D.E. 379).)

Medtronic now argues that SSI's Amended Complaint is insufficient to meet its burden on lost profits because none of the three Plaintiffs is either the owner or exclusive licensee of the '071 patent (and therefore has standing) and made sales of the ProDisc II outside of the United States (and therefore suffered loss sales).[12] The Court declines to address the merits of Medtronic's argument based on Medtronic's conduct during the

[12] Medtronic asserts that Synthes, Inc. does not own the '071 patent and is not a licensee; that Spine Solutions does not market or sell the ProDisc II; and that Synthes Spine did not have non-United States sales during the relevant period. (Medtronic Mot. 20.)

proceedings. Medtronic first raised this issue on the eve of trial, permitted SSI to amend its complaint, and declined the opportunity to extend the trial date to conduct further discovery into the matter. (See id. at 3-4 ("Both parties agreed [during the telephone conference] that all relevant discovery has been conducted in the case, that no new discovery would be needed, and that neither party would be unprepared for trial due to [SSI amending its complaint].").) Thus, Medtronic cannot now renew its corporate distinctions argument as a basis for its motion for JMOL. Accordingly, the Court DENIES Medtronic's motion as to lost profits.

B. New Trial

In addition to moving for JMOL, Medtronic requests a new trial. Under Federal Rule of Civil Procedure 59(a)(1)(A), a court may grant a new trial "on all or some of the same issues . . . after a jury trial, for any reason for which a new trial has herefofore been granted in an action at law in federal court." Under this standard, "a new trial is warranted when a jury has reached a 'seriously erroneous result' as evidenced by: (1) the verdict being against the weight of the evidence; (2) the damages being excessive; or (3) the trial being unfair to the moving party in some fashion, *i.e.*, the proceedings being influenced by prejudice or bias." Holmes v. City of Massillon, Ohio, 78 F.3d 1041, 1045-46 (6th Cir. 1996).

Medtronic argues that a new trial is warranted because (1) the Court denied Medtronic's motion *in limine* to exclude evidence that it copied a claim of the '071 patent into its patent application to provide an interference, (2) the Court excluded SSI's continuation application from trial, and (3) the Court denied Medtronic's motion *in limine* to preclude SSI's experts from testifying about Medtronic documents to support SSI's allegations that Medtronic copied the ProDisc II. Each issue is addressed in turn.

1. Medtronic Patent Applications

Medtronic asserts that SSI's introduction of Medtronic's continuation application was irrelevant and prejudiced the jury because SSI "insinuated" that Medtronic improperly copied the claims of the '071 patent. (Medtronic Mot. 22.) When prejudice "is cured by instructions of the court, [a] motion for a new trial should be denied." Holmes, 78 F.3d at 1047; see also United States v. Gomez-Pabon, 911 F.2d 847, 858 (1st Cir. 1990) ("There is ordinarily a presumption that a jury will follow [a court's] curative instructions."). Here, the Court instructed the jury that

> [d]uring the trial, you may have heard Spine Solutions' lawyer talk about the fact that Medtronic put into one of its own patent applications a claim identical to a claim in Spine Solutions' '071 patent. You should know that there is nothing wrong with Medtronic putting a claim of Spine Solutions' '071 patent into its own application. This was an

> appropriate way to attempt to start a proceeding in the Patent Office that is called an interference. Anything that you might have heard to the contrary is a misstatement of the law and you should disregard it.

(Jury Instructions 40.) This instruction squarely addressed Medtronic's concern regarding its copying of the '071 claim to provoke an interference and thus cured any prejudice Medtronic may have suffered.

Medtronic similarly requests a new trial on the basis that SSI argued during opening statements that Medtronic committed inequitable conduct in a patent that was not at issue at trial. The Court excluded the patent file history, however, and the parties and the Court agreed to admit only a redacted version of the patent to avoid confusion. (Trial Tr. Dec. 3, 2008, 1400:3-1401:24; 1419:1-1420:5.) Furthermore, the jury was instructed that it "must not consider as evidence any statements of counsel made during trial." (Jury Instructions 19.) Given these actions and curative instruction, the Court finds no prejudice to Medtronic and declines to grant a new trial on this basis.[13]

[13] Medtronic argues that SSI wrongly used Medtronic's copying of its claims as a basis for its willful infringement argument. SSI, however, used Medtronic's continuation application because it contained an assertion that the claims of the '071 patent were patentable. A party seeking an interference has no duty to "affirmatively represent that claims it has copied from an issued patent into its application are valid." Novo Nordisk A/S v. Bio-Tech. Gen. Corp, Ltd., 2003 WL 21383717, at *4 n.1 (D. Del. June 9, 2003). SSI's use of Medtronic's continuation application was relevant to its willful infringement claim because it evidences Medtronic's knowledge of the validity of the '071 patent.

2. SSI's Continuation Application

Medtronic next asserts that a new trial is warranted because the Court excluded SSI's continuation application. Medtronic argues that because the continuation application is directed to an artificial disc with a single anchor and that those claims were rejected based on non-spinal prior art, the application was relevant to its obviousness defense. As discussed during a sidebar at trial, the PTO examination was ongoing, the claims of the continuation application were different from those in the patent-at-suit, and introducing the continuation application would have confused the jury. (Trial Tr. Nov. 26, 2008, 776:21-782:17.) The Federal Circuit recently affirmed a district court's decision to exclude at trial evidence of a similar proceeding before the PTO. Callaway Golf Co. v. Acushnet Co., --- F.3d ---, 2009 WL 2481986, *9 (Fed. Cir. Aug. 14, 2009) (holding that the PTO's re-examination determinations "were of little relevance to the jury's independent deliberations on the factual issues underlying the question of obviousness" and that "the risk of jury confusion if evidence of the non-final PTO proceedings were introduced was high"). Moreover, the jury heard substantial evidence on the issue of non-spinal prior art; evidence of the PTO's reliance on additional non-spinal prior art from the toe and thumb would not have contributed anything new to the jury's analysis.

Accordingly, the exclusion of the continuation application does not entitle Medtronic to a new trial.

3. Expert Witness Testimony on Copying

Lastly, Medtronic argues that the Court's denial of its motion *in limine* to preclude SSI's experts from testifying about certain Medtronic documents to support its argument that Medtronic copied the ProDisc II. Medtronic contends that this denial was prejudicial because copying was not a proper issue for expert testimony. Medtronic objects to SSI remarking during closing arguments that Medtronic chose not to call any witnesses. In addition, Medtronic accuses SSI of improperly supplementing its expert reports after the close of discovery.

During trial, SSI's expert Ducheyne was qualified as an expert "in the field of orthopedic devices and their fixation." (Trial Tr., Dec. 1, 2008, 917:12-23.) Ducheyne then testified as to the process by which Medtronic considered various design options before settling on a single anchor design and its skepticism that such a design would provide adequate support. (Trial Tr., Dec. 1, 2008, 967:16-998:20, 1001:8-1010:8.) The Court admitted into evidence various documents related to these issues (Trial Tr. Dec. 1, 2008, 898:5-901:16), and Ducheyne's testimony was used to help the jury understand the technical aspects of the designs and the process by which Medtronic developed the Maverick as described in these materials.

Furthermore, the jury heard from fact witnesses on the issue of Medtronic's copying (see Trial Tr., Dec. 2, 2008, 1122:7-1150:9 (video deposition of Eisermann), 12736:7-1290:3 (video deposition of Medtronic Director of Marketing Christopher Hughes)), so SSI's case did not rely solely on Ducheyne.

Medtronic's additional arguments related to copying are unpersuasive. SSI's experts disclosed their supplemental reports following the Court awarding an extension of time for such disclosures. (See Order Granting in Part and Den. in Part Defs.' Mot. for a Protective Order and Granting in Part and Den. in Part Pl.'s Mot. to Compel and for Relief from the Pretrial Scheduling Order 5 (granting both parties sixty days to supplement their expert reports in response to any new information produced by Medtronic).) Although during closing arguments counsel for SSI wrongly indicated that Medtronic was unable to call fact witnesses regarding Medtronic's copying when the Court had precluded those witnesses from testifying, the Court instructed the jury to not consider as evidence statements made by counsel.[14] (Jury Instructions 19.)

For these reasons, Medtronic's motion for a new trial is DENIED.

[14] Likewise, Medtronic's contention that SSI's improper cross-examination of Cook merits a new trial is to no avail because the Court provided a curative instruction immediately following the cross-examination. (See Trial Tr., Dec. 3, 2008, 1611:13-1612:3.)

III. CONCLUSION

For the foregoing reasons, Medtronic's motion is DENIED in its entirety.

IT IS SO ORDERED this 20th day of August, 2009.

s/ JON PHIPPS McCALLA
CHIEF UNITED STATES DISTRICT JUDGE